REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. 1.112, are respectfully requested in light of the remarks which follow.

Claims 1-33 are currently pending. Claims 8, 9, 15-27, 32, and 33 stand withdrawn as directed to non-elected subject matter. Claims 29-30 are amended herein to address issues of antecedent basis, as depending on claim 28. Thus, no prohibited new matter has been added.

Objection to the specification

The specification stands objected to for the incorporation by reference of U.S. Provisional No. 60/267,488. Applicants submit this amendment is proper under M.P.E.P. § 214, as it clarifies the amendment to the specification reciting the U.S. provisional priority information timely requested by Applicant in the Utility Patent Application Transmittal Letter, filed with the present application on February 8, 2002.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-7, 10-14 and 28-31 stand rejected under 35 U.S.C. § 112, first paragraph, as the phrase " wherein the exogenous gene does not cross-hybridize with an homologous gene of the plant cell" is purportedly not supported by the specification. Applicants submit that the phrase "wherein the exogenous gene does not cross-hybridize with an homologous gene of the plant cell" is supported in the specification.

The subject matter of the claim need not be described literally (*i.e.*, using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement. M.P.E.P. § 2163.02. To this end, Applicants submit that the concept that the exogenous gene does not cross hybridize an homologous gene of the cell is adequately supported. Specifically, Applicant refers to the disclosure regarding the transformation of MinD/MinE of *Arabidopsis thaliana* into tobacco, for example, on page 7, lines 19-25, page 14, lines 10-27 and page 16, lines 5-6, providing examples where the MinD/MinE are transformed into tobacco and do not cross-hybridize. Page 16, lines 5-6, for example, states explicitly that "the AtMinE1 gene did not cross-hybridize with a tobacco homologue". The specification highlights the fact that cross-hybridization does not occur with the present invention, and states that "no cross-hybridization [of the AtMinD gene] was observed with wild-type tobacco RNA" on page 26.

Thus, Applicants submit that there is support in the specification for the language " wherein the exogenous gene does not cross-hybridize with an homologous gene of the plant cell" , and that no new matter is set forth via the previous Amendment.

Claims 1-7, 10-14 and 28-31 stand rejected under 35 U.S.C. § 112, first paragraph, as the Office asserts that the claims are drawn to a multitude of vectors encoding a derivative of the MinD protein, but that the specification only provides support for the SEQ ID NO:1 sequence. Applicants note that the subject matter of the claim does not need to be described literally (*i.e.*, using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement. The appropriate

vectors encoding a derivative of the *Arabidopsis* MinD protein, methods of its use, and cells and plants comprising it, would be easily determined by the skilled artisan through what was known in the art at the time the invention was filed. For example, the NCBI database provides the skilled artisan with the information needed to know which DNA molecules are encompassed by the claimed invention, or which sequences encode a derivative of the MinD protein. Applicant does not have to list each and every nucleotide sequence in order to determine which molecules are encompassed by the present invention. A combination of what is set forth in the specification and what was known in the art when the application was filed provide sufficient support.

Claims 1-7, 10-14 and 28-31 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while enabling for a vector encoding the *Arabidopsis* MinD protein, plants and cells transformed with it and a method of using it to produce a plant with one or few chloroplasts, purportedly fails to provide enablement for vectors comprising a gene encoding a protein with the same functional activity as the *Arabidopsis* MinD protein, plants and cells transformed with them and a method of using them to produce a plant with one or few chloroplasts. Applicants respectfully traverse.

As stated in *Ex parte Forman* (230 USPQ 546 1986) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of

the claims. As, the Office is aware, "[a] patent need not teach, and preferably omits, what is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986). The law does not require a specification to be a blueprint in order to satisfy the requirement for enablement under 35 U.S.C. § 112, first paragraph. Thus, not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be. *Staehelin v. Sech*er, 24 U.S.P.Q.2d 1513, 1516 (Bd. Pat. App. & Int. 1992).

The Office states that the specification does not enable genes that encode proteins with the same functional activity as the *Arabidopsis* MinD gene. Applicants submit that the skilled artisan would be able to indentify such genes without undue experimentation, as genes that encode proteins with the same functional activity as the *Arabidopsis* MinD gene are taught by the present specification.

The present specification discloses homologous genes and methods of their identification throughout the specification, at least at page 7-8, lines 26-10, and page 8-9, lines 19-10. Furthermore, the specification clearly defines functional activity as "results in the production of fewer and larger chloroplasts in the plant", page 13, lines 17-20. In fact, the specification provides guidance for determining whether the protein results in the production of fewer and larger chloroplasts in the plant (*see* page 14, lines 10-17, and page 15, lines 1-3). Applicants also refer to Figure 1, which represents an alignment of several MinD homologs. This alignment of MinD proteins identifies which MinD amino acid residues are conserved between species, and which MinD amino acid

residues are not conserved between species. To this end, the skilled artisan would also be able to determine any required amino acid substitutions to maintain MinD activity.

With regard to the MinD database, this database is merely an example of what was known in the art. Although the MinD database was created on October 7, 2002, sufficient information was available to one of skill in the art at the time of filing for the identification of proteins with the same functional activity as the *Arabidopsis thaliana* MinD gene, and in fact sequences in the MinD database were available prior to the filing date of the application. At the time of filing, in February 2002, one of skill in the art routinely compared amino acid sequences to identify conserved amino acids. To this end, the MinD database is a collection of such analyses which are routinely conducted by one of skill in the art.

Given the teachings regarding the gene and function of analogs and variants, the specification provides enablement for vectors comprising a gene encoding a protein with the same functional activity as the *Arabidopsis* MinD protein, plants and cells transformed with them and a method of using them to produce a plant with one or few chloroplasts. Accordingly, the specification enables any person skilled in the art to make and/or use the invention commensurate in scope with the claims. Applicants respectfully request that the rejection be withdrawn.

Claim Rejections Under 35 U.S.C. § 112 Second Paragraph

Claims 1-7, 10-14 and 28-31 stand rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite.

Claims 1, 5-7, 10-13 and 28-31 stand rejected for the recitation of the term "exogenous". The Office argues it is purportedly unclear as to what the gene is exogenous to. As exogenous refers to a gene which has been produced outside of an organism, the skilled artisan could determine that the gene is exogenous to the tobacco from reviewing the specification.

Claims 1, 10, and 28 stand rejected for the recitation of "a protein with the same functional activity as a protein encoded by the *Arabidopsis thaliana ... MinD* gene". It is purportedly unclear which protein encoded by the *MinD* gene is being referred to. Additionally, it is purportedly not clear what the exact function of the *Arabidopsis* MinD protein is. Applicants note that the function of the MinD protein is clearly described in the specification, at least at page 13, lines 18-21, as causing "the production of fewer and larger chloroplasts in the plant". With regard to the structure of MinD, this is known in the art. The specification on page 13 discloses that by a protein having the same functional activity as the *Arabidopsis thaliana* is meant a protein which when transformed into the nuclear genome of a plant results in the production of fewer and larger chloroplasts in the plant. Claims 1, 10, and 28 recite such proteins, regardless of whether they are named "MinD".

Claims 1, 10, and 28 stand rejected for the recitation of "wherein the exogenous gene does not cross-hybridize with an homologous gene of the plant cell", as it is

purportedly what level of hybridization is involved. Hybridization details are described in the specification at least a page 8, lines 19 to page 9, line 1, and furthermore are well known in the art. Applicants further refer to Example 4 on page 24-25, as showing hybridization, at moderate stringency, where the AtMinD gene does not cross hybridize with a tobacco MinD homolog.

Claims 5, 7, 11, 13, 29, and 31 are rejected for the recitation of "significant amount of homology to a gene from *Aridopsis thaliana*". Degrees of homology are discussed on page 8 of the specification, and appropriate levels of homology exemplified in the Examples of the present specification.

Claims 29-30 stand rejected for purportedly lacking antecedent basis for the term "vector of claim 28". Claims 29 and 30 are amended herein to provide antecedent basis in the preamble of these claims.

In light of the above remarks, Applicants request that the rejections under 35 U.S.C. § 112, second paragraph, be withdrawn.

Claims Rejections Under 35 U.S.C. § 102

Claims 1-7, 10-13 and 28-31 stand rejected under 35 U.S.C. §102(a) as purportedly anticipated by Colletti *et al.* (2000, *Curr. Biol.* 10:507-516).

Colletti *et al.* purportedly disclose vectors comprising the *Arabidopsis MinD* coding sequence in the sense or antisense orientation under control of the 35S promoter and *Arabidopsis* plants whose nuclear genome is transformed with the gene; these plants had large chloroplasts that were reduced in number. Applicants traverse.

"[A]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention as arranged in the claims." *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 U.S.P.Q. 253, 256 (Fed. Cir. 1985). Each element of the present claims is not set forth in the cited references.

The present independent claim 1 relates to a vector comprising an exogenous gene which encodes a protein which has the same functional activity as a protein encoded by the *Arabidopsis thaliana MinD* gene. When expressed in a plant cell, this exogenous gene enhances the efficacy of chloroplast transformation, and does not cross-hybridize with a homologous gene of the plant cell.

The vectors of Colletti are expressed in an *Arabidopsis* plant cell and would cross-hybridize with a homologous gene of the plant cell. Colletti *et al.* does not disclose the claim element that the exogenous gene does not cross-hybridize with a homologous gene of the plant cell. The fact that the gene does not cross-hybridize with a homologous gene of the plant cell is important to the present invention, and is not disclosed in the cited references. These are structural differences between the present invention and the vectors of Colletti, which render the claimed invention novel over the cited reference.

Claims 1-7, 10-13 and 28-31 stand rejected under 35 U.S.C. §102(a) as purportedly being anticipated by Kanamaru *et al.* (2000, *Plant Cell Physiol.* 41:1119-1128 and GenBank Accession No. AB030278, December 2000).

Kanamaru *et al.* purportedly disclose a vector comprising the *Arabidopsis MinD* gene under control of the 35S promoter. However, Kanamaru does not disclose that the exogenous gene does not cross-hybridize with a homologous gene of the plant cell.

Claims 1-2 and 5-7 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Huang *et al.* (1996, *J. Bacteriol.* 178:5080-5085).

Huang *et al.* does not disclose that the exogenous gene does not cross-hybridize with a homologous gene of the plant cell. As described in the present specification at least at Example 12 in which the *Arabidopsis MinE* gene was transformed into both tobacco and *Arabidopsis*, the claim limitations related to the exogenous genes are necessary to prevent gene silencing. Huang *et al.* do not recite all of the elements of the claimed invention, as this reference fails to recite the system of increased efficiency and methods of achieving same.

In light of the above, Applicants respectfully request that the rejection under 35 U.S.C. § 102, be withdrawn.

CONCLUSION

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, a Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (703) 836-6620 so that prosecution of the application may be expedited.

Respectfully submitted,

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